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| CHARLOTTE, NC 28280-4000 | | | | |
| EXAMINER | | | | |
| FOX, DAVID T | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1638 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,430

Applicant(s)

WERNER ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE(1) MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8 (in part), 9-13, 18-19 (in part), 20, 30-34 (in part) and 36 (in part), drawn to a method for hybridizing a first and second transgenic plant, each containing a genetic endowment which is insufficient to produce a desired product in the plant containing only one genetic endowment, wherein the seed or seedling produced by said hybridization produces the desired product, wherein the desired product is isolated from the seed or seedling, and wherein the genetic endowment comprises a replicating DNA molecule such as an autonomous plasmid and a site-specific recombinase system.

Group II, claim(s) 1-8 (in part), 14-17, 18-19 (in part), 21-23, 30-34 (in part) and 36 (in part), drawn to a method for hybridizing a first and second transgenic plant, each containing a genetic endowment which is insufficient to produce a desired product in the plant containing only one genetic endowment, wherein the seed or seedling produced by said hybridization produces the desired product, wherein the desired product is isolated from the seed or seedling, and wherein the genetic endowment comprises a replicating RNA molecule such as an RNA virus replicon.

Group III, claim(s) 1-8 (in part), 24, 27-29, 30-34 (in part) and 36-37 (in part), drawn to drawn to a method for hybridizing a first and second transgenic plant, each

Art Unit: 1638

containing a genetic endowment which is insufficient to produce a desired product in the plant containing only one genetic endowment, wherein the seed or seedling produced by said hybridization produces the desired product, wherein the desired product is isolated from the seed or seedling, wherein the genetic endowment comprises a replicating DNA or RNA molecule, and further comprising a toxin-encoding gene preventing the development of a mature plant from the seed produced by the hybridization.

If Group III is elected, the following Election of Species is applied:

Species A. Replicating DNA molecules, claims 1-8, 24, 27-34 and 36-37.

Species B. Replicating RNA molecules, claims 1-8, 24, 27-34 and 36-37.

Group IV, claim(s) 1-4 (in part), 25-26, 30-34 (in part), and 36-37 (in part), drawn to a method for hybridizing a first and second transgenic plant, each containing a genetic endowment which is insufficient to produce a desired product in the plant containing only one genetic endowment, wherein the seed or seedling produced by said hybridization produces the desired product, wherein the desired product is isolated from the seed or seedling, and wherein the genetic endowment further comprises a toxin-encoding gene preventing the development of a mature plant from the seed produced by the hybridization.

Group V, claim(s) 35, drawn to an isolated polymer.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are linked by the technical feature of a method for hybridizing a first and second transgenic plant, each containing a genetic endowment which is insufficient to produce a desired product in the plant containing only one genetic endowment, wherein the seed or seedling produced by said hybridization produces the desired product, and wherein the desired product is isolated from the seed or seedling. However, this feature is not special because it does not constitute an advance over the prior art. EP 1,048,734 issued 02 November 2000 (THE SCRIPPS RESEARCH INSTITUTE), submitted by Applicant, teaches the hybridization of two plants, one containing a genetic endowment encoding a heavy chain of an immunoglobulin, and the second containing a genetic endowment encoding a light chain of an immunoglobulin, to produce progeny seeds and plants which produce a multimeric immunoglobulin protein which may be isolated from the progeny plants (see, e.g., claims 58-62; page 3 of the specification, lines 5-20; page 34 of the specification, line 38 through page 35, line 42; and Figure 3).

Furthermore, the inventions are not linked by a single special technical feature because each requires biochemically and physiologically divergent method steps and starting materials, each not required by the other.

Groups I and III(A) involve replicating DNA molecules and site-specific recombinase systems not required by any other group.

Groups II and III(B) involve replicating RNA virus replicons not required by any other group.

Groups III and IV involve toxin-encoding genes and methods for evaluating seed sterility, not required by any other group.

Group V involves isolated polymers, not required by any other group.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (b) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (c) the prior art applicable to one invention would not likely be applicable to another invention;
- (d) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

Art Unit: 1638

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-

Art Unit: 1638

0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 12, 2008

/David T Fox/

Primary Examiner, Art Unit 1638